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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,718	02/13/2002	Shubh D. Sharma	70025-02-US02	9717

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/049,718

Applicant(s)

SHARMA ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,9-18 and 26-63 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-5 and 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,18,26-29 and 33 is/are rejected.
- 7) ☒ Claim(s) 30-32 and 34-63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2005 has been entered.

2. Applicant's election of Group II in the reply filed on May 10, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election of species requirement set forth in the Office action mailed March 10, 2004 is withdrawn. The search and examination has been extended to all of the peptide formulas recited in claim 18 and to all of the claims dependent upon claim 18.

Claims 1, 3-5, and 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 10, 2004.

3. Claim 47 is objected to because of the following informalities: At claim 47, line 1, "an" (first occurrence) should be changed to "a". Appropriate correction is required.

4. Claim 44 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. Note that claim 44 is dependent upon both claim 18 and upon claim 42. See MPEP § 608.01(n), especially the example at section (I)(B)(3).

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5. Instant claims 2, 7, 8, 18, 20, 26-33, and 37-40 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/148,994 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose peptides in general in which the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain, and does not disclose each of the generic formulas recited in instant claim 18, and in particular does not disclose the formula corresponding to the elected species  $R_1$ -Bbb-Aaa-Ccc- $R_2$ . Accordingly, the Giblin et al article (PNAS, Vol. 95, pages 12814-12818) is available as prior art against these claims under 35 U.S.C. 102(b).
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 2, 18, 26-29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by the Giblin et al article (PNAS, Vol. 95, pages 12814-12818). The Giblin et al article teaches the peptides NAc-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH<sub>2</sub> and NAc-Cys-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH<sub>2</sub>, which correspond to Applicants' peptide of the formula  $R_1$ -Fff-Aaa-Ggg-Ccc- $R_5$ , where NAc-Cys-Glu-His and NAc-Cys-Cys-Glu-His, respectively, are  $R_1$ ; D-Phe is Fff; Arg is Aaa; Trp is Ggg; Cys is Ccc; and Lys-Pro-Val-NH<sub>2</sub> is  $R_5$  which is a substituted amide or which comprises an L- or D-amino acid. The peptides are complexed and cyclized with Re or Tc. The complexed peptides are specific for  $\alpha$ -MSH receptors. See, e.g., the Abstract; page 12815, column 1, first full paragraph; and Figure 1. In view of the similarity in structure and function between the peptides of the Giblin et al abstract and Applicants' claimed peptides, the peptides of the Giblin et al abstract are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at

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least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of the Giblin et al abstract and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptides of the Giblin et al abstract.

8. Applicant's arguments filed March 3, 2005 have been fully considered but they are not persuasive.

The examiner maintains his position that the instant claims are not entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/148,994. The examiner agrees that in order to satisfy the written description test of 35 U.S.C. 112, first paragraph, claim language does not need to be literally recited in a priority document. However, the concept of coextensive biological-function and metal ion-binding domains is not disclosed in the provisional application, either explicitly or using equivalent terminology. It is not probable that one of ordinary skill in the art, upon looking at the specific compounds disclosed in Table 1 of the provisional application, would recognize that Applicants had invented a generic class of compounds in which at least a portion of the biological-function domain was co-extensive with at least a portion of the metal ion-binding domain. This concept can not be readily extracted from the specific compounds listed in the table. The concept is not present in "full, clear, concise, and exact terms" as required by 35 U.S.C. 112, first paragraph. Further, even though Table 1 of the provisional application may disclose hundreds of specific compounds, the instant generic claims embrace many more compounds than the particular ones disclosed in the table.

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The disclosure of a limited number of species does not inherently or implicitly constitute disclosure a more general class of compounds.

As support for the current claim language, Applicants cite to portions of the provisional application which discuss libraries of compounds in which the metal ion-binding amino acid sequence in the peptides forms a reverse turn structure upon complexation with a metal ion. However, these sections of the provisional application are not equivalent in scope to the current claim language. The current claim language is not limited to peptides which form reverse turn structures upon complexation with metal ions. Again, disclosure of a species or a subgenus does not support claim language drawn to a broader genus.

The rejection based upon the Giblin et al article (PNAS, Vol. 95, pages 12814-12818) is maintained for the reasons of record, and especially for the reasons set forth in section 3 of the Advisory action mailed April 1, 2005. Similarity in structure and function between the peptides of the Giblin et al article and Applicants' claimed peptides, and in particular the fifth peptide formula of Applicants' claim 18, is sufficient to establish prima facie anticipation. Applicants have not demonstrated that there is some claimed feature not possessed by the peptides of the Giblin et al article.

9. Stuttle (U.S. Patent No. 5,395,609) is cited as art of interest, teaching the peptide RGDSYC (see, e.g., column 3, line 11), and in general teaching that peptides according to the invention can be labeled with technetium (see, e.g., column 2, lines 13-17). The RGDSYC peptide corresponds to Applicants' formula  $R_4\text{-Eee-Bbb-Ccc-R}_2$ . However, Stuttle does not actually teach technetium-labeled RGDSYC, does not suggest that such a technetium-labeled peptide will bind to a melanocortin receptor, and does not suggest that such a technetium-labeled

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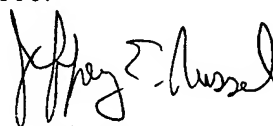
peptide will be more specific for a melanocortin receptor than the non-labeled peptide.

Accordingly, Stuttle is not deemed to suggest the instant claimed invention.

10. Claims 30-32, 34-43, 45, 46, and 48-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 44 and 47 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
July 1, 2005